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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,719	08/22/2000	Margret Hoehe	101195-2	8381

7590 08/20/2003

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New York, NY 10017

EXAMINER
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BRANNOCK, MICHAEL T

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 08/20/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/582,719

Applicant(s)

HOEHE ET AL.

Examiner

Michael Brannock

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) 1-42 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

Applicant is notified that the amendments put forth in Papers 18 (9/9/02), 20 (9/3/03) and 22 (5/06/03) have been entered in full. Applicant's timely response (Paper 18) to the restriction requirement (Paper 16, 6/6/02) is noted; however, due to Applicant's amendments and arguments, the examiner deems it necessary to issue a new restriction requirement.

#### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1-12, claim(s) 1-23 and 31, as each group relates to at least one of position 159, 245, 565, 934, 1120, 1221, 1541, 1568, 1839, 2110, 2640, or 2826, drawn to disclosed polynucleotide variants of an adrenergic receptor and methods of determining a predisposition to a disease.

Group 13-24, claim(s) 24-26, 30, 33, as each group relates to at least one of position 159, 245, 565, 934, 1120, 1221, 1541, 1568, 1839, 2110, 2640, or 2826, drawn to methods of identifying therapeutic agents that act on an adrenergic receptor.

Group 25-36, claim(s) 27-29 and 32, as each group relates to at least one of position 159, 245, 565, 934, 1120, 1221, 1541, 1568, 1839, 2110, 2640, or 2826 drawn to methods of predicting individual responsiveness to therapeutic agents.

Group 37-44, claim(s) 34-42, as each group relates to at least one of position 159, 245, 565, 934, 1120, 1221, 1541, 1568, 1839, 2110, 2640, or 2826 drawn to undisclosed polynucleotide variants of an adrenergic receptor.

The inventions listed as Groups 1-44 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special

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technical features for the following reasons: pursuant to 37 C.F.R. 147(d), this Authority considers that the main invention in the instant application comprises the first recited product, namely a polynucleotide comprising at least one base substitution at one or more positions including position 159 of SEQ ID NO: 1, and the first recited method of using that product, namely in the process determining a predisposition to a disease associated with the polynucleotide. Note that there is no method of making the polynucleotide. Also included in this group are vectors and host cells comprising the polynucleotide. Further pursuant to 37 C.F.R. 1.475 (b)-(d), the ISA/US considers that the materially and functionally dissimilar product of Groups 2-12 and 37-44 and the materially and functionally dissimilar methods of Groups 13-36 do not correspond to the main invention. This Authority therefore considers that the several inventions do not share a special technical feature within the meaning of PCT Rule 13.2 and thus do not relate to a single general inventive concept within the meaning of PCT Rule 13.1

The claims of Groups 1-44 encompass an indecipherable number of patentably distinct alleles of an adrenergic receptor. Applicant is required to elect one allele, i.e., one polynucleotide sequence that would be present on one chromosome. Thus, if Applicant elects Group I, it is understood that any combination of the twelve positions could be elected, so long as the elected allele includes a substitution at position 159, and so long as only one allele is elected. As Applicant points out, each allele is a non-obvious variant of the others, each apparently resulting in distinct phenotypes, and thus lack a special technical feature, and are thus patentably distinct. Further, the technical feature of generic claims 1 and 9, i.e., that alleles of an adrenergic receptor are associated with diseases, is not a special technical feature, under PCT

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Rule 13.2, because this technical feature was known in the prior art, as set forth previously, e.g. TURKI et al.

This application contains claims directed to the following patentably distinct species of the claimed invention: the claims are directed to an indecipherable number of diseases.

Applicant is required to elect one species of disorder, i.e., that representing a single identifiable patient population, that Applicant believes is associated with the elected allele.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, all claims appear to be generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

A telephone call was made to Theodore on Gottlieb to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Conclusion***

Please note the new official fax number below:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (703) 306-5876. The examiner can normally be reached on Mondays through Thursdays from 8:00 a.m. to 5:30 p.m. The examiner can also normally be reached on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564.


Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB



8/14/03



YVONNE EYLER, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600